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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/014,812 | 12/14/2001 | Stephen Palmer | PALMER=1 | 1664 |

1444 7590 02/20/2004

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| EXAMINER | |
|---|---|
| LIU, SAMUEL W | |
| **ART UNIT** | **PAPER NUMBER** |
| 1653 | |

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/014,812 | PALMER ET AL. | |
| | Examiner | Art Unit | |
| | Samuel W Liu | 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6 and 28-30, drawn to a method of ovulation induction in a female host comprising administering to said host only a non-polypeptide cAMP modulator at the time point, i.e., prior to the luteal phase of the host's ovulatory cycle, are classified in class 514, subclasses 2, 15 and 21, class 435, subclass 19, and class 530, subclasses 300.

II. Claims 7-8 and 13-18, drawn to a method of ovulation induction in a female host comprising administering to said host (i) a non-polypeptide cAMP modulator, and (ii) an agent that is follicle stimulating hormone (FSH), are classified in class 514, subclasses 2, 15 and 21, class 435, subclass 19, and class 530, subclasses 313 and 398.

III. Claims 7, 9 and 13-18, drawn to a method of ovulation induction in a female host comprising administering to said host (i) a non-polypeptide cAMP modulator, and (ii) an agent that is clomiphene (*a compound stimulating FSH production*), are classified in class 514, subclasses 2, 15 and 21, class 435, subclass 19, and class 530, subclasses 313 and 398.

IV. Claims 7, 10 and 13-18, drawn to a method of ovulation induction in a female host comprising administering to said host (i) a non-polypeptide cAMP modulator, and (ii) an agent that is a selective estrogen receptor modulator (*an agonist or an antagonist to the estrogen receptor*), are classified in class 514, subclasses 2, 15 and 21, class 435, subclass 19, and class 530, subclasses 313 and 398.

V. Claims 7 and 11-18, drawn to a method of ovulation induction in a female host comprising administering to said host (i) a non-polypeptide cAMP modulator, and (ii) an agent that is an aromatase inhibitor (*a compound decreasing plasma*

*estrogen level*), are classified in class 514, subclasses 2, 15 and 21, class 435, subclass 19, and class 530, subclasses 313 and 398.

VI. Claims 19-21, drawn to a method of ovulation induction in a female host comprising administering to said host a non-polypeptide cAMP modulator at the time point of an existing ovulation induction at which human chorionic gonadotropin (hCG) or luteinizing hormone (LH) is administered to said host, are classified in class 514, subclasses 2, 15 and 21, class 435, subclass 19, and class 530, subclasses 313 and 398.

VII. Claims 22-24, drawn to a non-polypeptide cAMP modulator and a pharmaceutical composition comprising the modulator thereof, are classified in class 514, subclass 2, and class 424, subclass 278.1.

VIII. Claims 25-26, drawn to a process of using a non-polypeptide cAMP modulator in a pharmaceutical composition to treat anovulatory disorder state and preparing the composition thereof, are classified in class 514, subclasses 2, and class 424, subclasses 94.6 and 278.1 .

IX. Claim 27, drawn to a method of collecting oocytes for in vitro fertilization comprising administering to a subject the non-polypeptide cAMP modulator, is classified in class 435, subclasses 366, 325 and 364, and class 514, subclasses 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, IV, V, VI, VIII and IX are directed to different and/or distinct methods as stated above. Although there are no provisions under the section for "Relationship of Invention" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between the methods of Inventions I, II, III, IV, V, VI, VIII and IX since they constitute patentably distinct inventions comprising distinct/different

methodologies, starting material, objectives, technical considerations, ingredients, endpoint or/and treatment outcome. Therefore, each method is patentably distinct. It is of note that (*i*) Invention I and Inventions II, III, IV and V are different methods in that they comprise distinct compositions to be administered to said host, e.g., the composition of Invention I ONLY comprises the non-polypeptide cAMP modulator whereas the composition of invention II, III, IV and V comprises an agent that is FSH, clomiphene, a selective estrogen receptor agonist or antagonist, and an aromatase inhibitor, respectively, *in addition to* comprising the non-polypeptide cAMP modulator; these agents are structurally and functionally distinct/different, e.g., the aromatase inhibitor reduces plasma estrogen while FSH tends to enhance estrogen release from ovarian; and (*ii*) Although both Inventions I and V methods comprising administering to the host a non-polypeptide cAMP modulator, the Inventions I and V are distinct methods since they differ at the time point for the administration, which would result in distinct starting point and therefore different outcome.

Invention VII is related to Invention VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the modulator of Invention VII can be used to raise an antibody that binds to the modulator thereof, for example.

Invention VII is also related to Inventions I-VI and IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the pharmaceutical composition comprising the modulator of Invention VII has an alternative use in the process of Invention VIII; i.e., treating an anovulatory disorder state, for example.

***Additional Election Under 35 USC 121***

Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single ovulation induction agent to which claims are restricted; and (2) to list all claims readable thereon.

When Group I is elected, applicant is required to elect one non-polypeptide cAMP modulator, i.e., a phosphodiesterase inhibitor compound from claims 28, or claim 29, or claim 30, since the compounds recited in claims 28-30 are structurally and/or functionally distinct/different, e.g., N-hydroxy-5,6-dimethoxy-benzo[b]thiophene-2-carboximidamide hydrochloride (Org-30029) is a $Ca^{2+}$ sensitizer whereas org-20241 is an inhibitor for both phosphodiesterase III and phosphodiesterase IV. Thus, the compounds are patentably distinct. Note that this is not species election but an additional election under 35 USC 121 because of the reason stated above.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The examiner can normally be reached Monday-Friday 9:00 -5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

SWL

Samuel W. Liu, Ph.D.

February 12, 2004